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October 18, 2001

Mr. Robert L. Stephenson II, M.P.H.
Director, Division of Workplace Programs, CSAP
5600 Fishers Lane, Rockwall II, Suite 815
Rockville, MD 20857

Re: Comment to Proposed Regulations (66 FR 43876)

Dear Mr. Stephenson:

The purpose of this letter is to comment on the proposed regulations "Mandatory Guidelines for Federal Workplace Drug Testing Program" published on August 21, 2001, at 66 Fed. Reg. 43876.

We represent Julia Jones. Ms. Jones is a former Frontier Airlines' flight attendant. She was terminated from her employment with Frontier on February 25, 2000. She was terminated for having provided a urine sample with a creatinine reading of 4.9 mg/dl and a specific gravity of 1.001. Ms. Jones is not an illegal drug user. We are in the midst of litigation concerning this termination.

FACTUAL BACKGROUND

On February 17, 2000 (the date her urine sample which is at issue was provided), Ms. Jones weighed approximately 115 pounds and stood 5'7" high; she wore a size zero. She went on hormone replacement therapy in approximately November of 1999, when she began menopause.

At the time of providing her urine sample at issue, Ms. Jones ate a non-beef, moderate protein diet. Ms. Jones habitually drinks (and has for years) two cups of coffee in the morning and approximately 150-200 ounces of water daily.

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Ms. Jones also has a family history of an overactive bladder which has required cystoscopies (a procedure by which the opening from the bladder into the urethra is enlarged). She has undergone three or four in her lifetime. Both of her children have undergone the same procedure as have her mother, sister, grandmother and two aunts.

Ms. Jones was hired by Frontier as a Flight Attendant in August, 1997. Her performance had always been more than satisfactory. Between her hire date and February 17, 2000, she had been subject to one random drug test. She passed that test as well as her pre-employment drug test.

In the fall of 1999, Ms. Jones underwent sinus surgery. She was off of work for twelve weeks. Upon her return to work, Ms. Jones was subject to a drug test. This drug test was not a mandatory test under the federal regulations because it was not for one of the five specified reasons which require testing (reasonable suspicion, post-accident, pre-employment, "return to duty" as specifically defined or random).

Ms. Jones provided her urine sample at approximately 8:30 a.m. on February 17, 2000; it was a split sample. The temperature of the sample was within normal limits. Exhibit 1, p. 2. On February 18, 2000, the laboratory tested Bottle A and found it to have a creatinine level of 4.9 mg/dl and a specific gravity of 1.001 (*Id.* at 8); all immunoassay drug screens were within normal limits (*Id.*) .

The laboratory which performed the urine test has provided Ms. Jones the standard deviations for the instruments used on her sample. The standard deviation for creatinine was as high as 0.59 (on one control) and 0.185 (on the other); the standard deviation for specific gravity was 0.0002 (on one control) and 0.000 (on the other). Ex. 2. In addition, the laboratory's refractometer used to measure the specific gravity of Ms. Jones' urine had divisions of .002. Ex. 3, p. 2. The visual scale had lines at 1.000 and 1.002. *Id.* Any reading between those lines was interpreted as a 1.001 (*Id.*); therefore, urine with specific gravity of 1.0001 was read the same as urine with a specific gravity of 1.0019.

In March and April, 2001, Ms. Jones provided urine samples at four different collection sites. The "validity" testing (Ex. 4) showed:

Lab	Col. Date	Direct Ob.	Creatinine	Specific Gravity
LabOne	3/24/01	Yes	4.5	1.002
Quest Labs	3/29/01	No	4.1	1.002
Quest Labs	4/6/01	No	5.7 mg/dl	1.002
Clinical Ref. Lab.	4/6/01	Yes	6	1.001

Drug tests (both immunoassay and GC/MS) were negative for all five screens. Ex. 4.

On September 28, 2001, Ms. Jones' Bottle B was finally tested. It showed a creatinine of 2.9 mg/dl and a specific gravity of 1.002. Ex. 5. All drug screens (immunoassay and GC/MS) were negative. *Id.* Her ph was 6.4 and chromium and nitrite were not present. *Id.*

COMMENTS TO PROPOSED REGULATIONS

We are aware that other commentators, in particular the Airline Pilots Association and the Transportation Trades Department of the AFL-CIO (collectively referred to as "ALPA"), will be discussing the validity of the studies upon which these proposed regulations are based. We will not duplicate that detailed analysis here but hereby incorporate ALPA's comment.

We will state that we believe that the studies upon which the "substitution" criteria is based are not forensically sound. In particular, the DOT water-loading study referred to in this notice of proposed revisions did not involve the use of split samples. Without the use of split samples, the study is meaningless because laboratory variances could have resulted in the split samples having different findings: one "valid" and the other "substituted". Indeed, the urine of one participant nearly met the criteria for being "substituted"; if a split sample had been tested, it is possible that this participant could have met the "substituted" criteria. Given this, the DOT water-loading study has been criticized by at least one Medical Review Officer. 12 MRO Alert 3, *The MRO's Oversight of the Referral Physician,* p. 4 (April 2001) (Ex. 6).

In addition, as the above findings evince, it is physiologically possible for a human to produce urine which meets the "substituted" criteria. Ms. Jones' Bottle A test results shows this and on four separate occasions (two of which were under direct observation) her urine nearly met the substitution criteria. Given that no laboratory procedure is absolutely accurate (as demonstrated by the standard deviations at the laboratory which tested Bottle A and the divergent readings of Ms. Jones' Bottles A and B), any one of her five urine samples could have met the substituted criteria set forth in proposed section 2.4(g)(3). They all meet the "dilute" criteria as set forth in proposed section 2.4(g)(4).

Because employers – such as Frontier – have a practice of terminating employees who innocently meet the "substituted" criteria, mandating validity testing illegitimately jeopardizes the employment of countless individuals. This practice exists despite the fact that there is no requirement in the federal regulations (existing or proposed) which requires termination for meeting the "substitution" criteria. This Department cannot ignore this and must adopt regulations which take into account this practice.

Moreover, given the lack of scientific study on why some people – albeit a small minority – do produce urine which meets the substitution criteria, it is forensically unsound to mandate validity testing and "substituted" criteria. Indeed, we are unaware of any scientific study on the effect of hormone replacement therapy [or on small framed women (such as Ms. Jones) who eat a non-beef diet, consume coffee and large amounts of water], on creatinine levels. In the absence of such studies, mandating validity testing and substitution criteria is again unwise.

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Thank you for your consideration in this matter.

Very truly yours,

THE FRICKEY LAW FIRM

Mark E. Rau by JJF

Mark E. Rau, Esq.

cc: Ms. Julia Jones (w/o enclosures)
Suzanne Kalfus, Esq. (ALPA) (w/enclosures)
Ms. Heather Healey (Assoc. of Flight Attendants) (w/enclosures)
Vina Spiehler, PhD (w/enclosures)

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NOTE

The comments submitted by the Frickey Law Firm included 6 exhibits that have not been placed on this website.

Exhibits 1 to 5 are documents associated with a data package and contain personal information that may be withheld from public review.

Exhibit 6 is the April 2001 issue of MRO Alert and is available from the American Association of Medical Review Officers.